K041663 1/2

SEP 16 2004

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of ALLOMATRIX® TCP, ALLOMATRIX® w/ CaSO4 Filled TCP, and ALLOMATRIX® PLUS CBM.

Submitted By:	**Wright Medical Technology, Inc.**
Date:	September 15, 2004
Contact Person:	**Brian Young** Director, Regulatory Affairs
Proprietary Name:	**ALLOMATRIX® TCP, ALLOMATRIX® w/ CaSO4 Filled TCP, and ALLOMATRIX® PLUS CBM**
Common Name:	Bone Void Filler
Classification Name and Reference:	Filler, Calcium Sulfate Preformed Pellets – Class II, 888.3045
Device Product Code and Panel Code:	Orthopedics/MQV

DEVICE INFORMATION

A. INTENDED USE

ALLOMATRIX® TCP, ALLOMATRIX® w/ CaSO4 Filled TCP and ALLOMATRIX® PLUS CBM are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. ALLOMATRIX® TCP, ALLOMATRIX® w/ CaSO4 Filled TCP and ALLOMATRIX® PLUS CBM are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

B. DEVICE DESCRIPTION

ALLOMATRIX® TCP, ALLOMATRIX® w/ CaSO4 Filled TCP and ALLOMATRIX® PLUS CBM come in the form of a kit with a premeasured powder, TCP and/or CBM chips, premeasured mixing solution, and the tools necessary to mix the components. After the powder is hydrated using all the mixing solution supplied in the kit, the resultant putty can then be handled and placed in the appropriate bone voids. This product is supplied sterile for single patient use.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

ALLOMATRIX® TCP, ALLOMATRIX® w/ CaSO4 Filled TCP and ALLOMATRIX® PLUS CBM were found to be substantially equivalent to the predicate devices. The safety and effectiveness of ALLOMATRIX® TCP, ALLOMATRIX® w/ CaSO4 Filled TCP and ALLOMATRIX® PLUS CBM is adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

Osteoinductivity Potential

Each lot of DBM incorporated into ALLOMATRIX® TCP, ALLOMATRIX® with CaSO4 Filled TCP and ALLOMATRIX® Plus CBM (hereafter ALLOMATRIX® Putty Products) is assayed *in vitro* for a native protein as a surrogate test marker for osteoinductive potential.[1] Results from this immunoassay were correlated to the athymic rat model for the DBM alone and the ALLOMATRIX Putty Products.[2] Testing each lot of DBM with this immunoassay assures that only DBM with osteoinductivity potential is used in the ALLOMATRIX® Putty Products. Although only one native protein is used as the test marker, it is the combination of various proteins in the DBM that is responsible for its osteoinductivity potential. The combination of DBM, CBM, and binding medium has not been evaluated for osteoinductivity; therefore, it is unknown to what extent the formulation components may alter the osteoinductive character of the DBM. Additionally, it is unknown how osteoinductivity potential, measured by this surrogate immunoassay, will correlate with human clinical performance of the Allomatrix Putty Products.

1 Data on file at Wright Medical Technology, Inc.

2 Lindholm TS, Urist MR. A quantitative analysis of new bone formation by induction in compositive grafts of bone marrow and bone matrix, *Clin Orthop* 1980 Jul-Aug;(150):288-300.

Viral Inactivation Validation

The method for processing the DBM and CBM contained in ALLOMATRIX® TCP, ALLOMATRIX® w/ CaSO4 Filled TCP and ALLOMATRIX® PLUS CBM was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes, and genomes were evaluated. The viral inactivation testing demonstrated suitable viral inactivation potential of the processing method for a wide spectrum of potential human viruses.

Product Performance Testing

Performance of ALLOMATRIX® TCP, ALLOMATRIX® w/ CaSO4 Filled TCP and ALLOMATRIX® PLUS CBM were evaluated in a canine model by radiographic and histological methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

Mr. Brian J. Young
Director, Regulatory Affairs
Wright Medical Technology
5677 Airline Road
Arlington, Tennessee 38002

Re: K041663
ALLOMATRIX® TCP, ALLOMATRIX® w/ CaSO4 Filled TCP, and
ALLOMATRIX® PLUS CBM
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV
Dated: June 14, 2004
Received: June 18, 2004

Dear Mr. Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K041663

Device Name: ALLOMATRIX® TCP, ALLOMATRIX® w/ CaSO4 Filled TCP and ALLOMATRIX® PLUS CBM

Indications for Use:

ALLOMATRIX® TCP, ALLOMATRIX® w/ CaSO4 Filled TCP, and ALLOMATRIX® PLUS CBM are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. ALLOMATRIX® TCP, ALLOMATRIX® w/ CaSO4 Filled TCP and ALLOMATRIX® PLUS CBM are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Prescription Use X
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041663